

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 10 and 27-157 are pending in the application, with 10, 27, 41, 65, 74, 85, 95, 115, 127, 136 and 148 being the independent claims. Claims 10, 27-94 and 148-157 have been withdrawn from examination as being directed to a non-elected invention. Claims 95, 98, 101, 104, 115, 117 and 127 have been amended for clarity. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 95-135 under 35 U.S.C. § 112, second paragraph, as being indefinite. Applicants respectfully traverse the rejection.

Specifically, the Examiner stated that claims 95-126 are indefinite due to the phrase "allow gaps of up to 5% of the total number of residues" and the recitation of the "Bestfit" program in claims 95, 98, 101, 104, 115 and 117. The Examiner also questioned whether the length of each gap could be 5% or less of the amino acid residues or whether the total number of gaps represented 5% or less of the amino acid residues. The Examiner further stated that the determination of percent identity may vary depending upon the version of the Bestfit® program used and thus, the claims should recite the algorithm used in the percent identity calculation.

Regarding the phrase "allow gaps of up to 5% of the total number of residues," in order to expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have amended the claims by inserting the phrase "amino acid" before the term "residues" so that the intended residues are clear.

Regarding the length of the gaps, as indicated in claims 95, 98, 101, 104, 115 and 117, each of the claims recites a sequence "at least 95% identical" to a reference sequence, and thus, the total gap length allowed is up to 5% of the total number of amino acid residues.

Regarding the version of the Bestfit[®] program, Applicants note that the specification, pages 23 and 38, states that the version used to calculate percent identity is version 8. More specifically, Wisconsin Sequence Analysis Package, Version 8 for Unix, Genetics Computer Group, University Research Park, 575 Science Drive, Madison, WI 53711. Since the claims are not read in a vacuum, but are read in light of the specification, one skilled in the art would know how to use the Bestfit[®] program as intended in the claims and thus, the recitation of a particular algorithm is not required. *See* MPEP § 2173.05(a).

The term "Bestfit[®]" has been designated as a trademark as suggested by the Examiner. "Bestfit[®]" represents computer software for use on personal computers for use in statistics or statistical analysis, namely, for statistical probability distribution, for use in business, science and engineering.

The Examiner stated that claim 127 is rendered indefinite due the terms "first" and "second" which render the claims confusing. The Examiner suggested removing the terms "first" and "second."

The Examiner's suggestion is appreciated. However, Applicants believe that the claim will be unclear if these terms are removed. Thus, to address the Examiner's concern and in order to

expedite prosecution and without acquiescing in the propriety of the rejection, Applicants have amended claim 127 to indicate that it is the second nucleotide which consists of the nucleotide sequence.

In light of the amendments to the claims and the arguments presented above, Applicants respectfully request withdrawal of the rejection.

Rejections under 35 U.S.C. § 102(a)

The Examiner rejected claims 95-107, 109-113, 115-119, 121-125, 127, 128, 130-134, 136-140 and 142-146 under 35 U.S.C. § 102(a) as being unpatentable over Davies *et al.* (*Nature* 385: 820-823 (Feb. 1997)). The Examiner objected to claims 108, 120, 129 and 141 since they depend from rejected claims. Applicants respectfully traverse the objection and rejection.

The Examiner stated that Davies *et al.* "disclose an isolated polynucleotide which is 100% identical to SEQ ID NO:41," "an amino acid sequence which is 100% identical to SEQ ID NO:42," a vector, a host cell and a method of making the polypeptide (Office Action, page 4). In addition, the Examiner asserted that since "the polynucleotide was inserted into a vector, which comprises nucleotides encoding regulatory sequences and proteins," then the isolated polynucleotide of Davies *et al.* "contains a heterologous regulatory sequence" (Office Action, page 4). Applicants respectfully traverse the rejection.

Applicants respectfully assert that the use of Davies *et al.* as a reference under 35 U.S.C. § 102(a) is not proper, because the reference is Applicants' disclosure of their own work. Although Davies *et al.* lists co-authors in addition to Applicants, a rejection under 35 U.S.C. § 102(a) may still be overcome by establishing that the portions of the reference pertinent to the

claimed invention describe Applicants' own work. See *In re Katz*, 215 USPQ 14 (CCPA 1982). In his attached Declaration under 37 C.F.R. § 1.132, Applicant Ewen F. Kirkness states that co-authors Davies and Hales performed electrophysiological assays which, although pertinent to the conclusions reached in the reference, do not amount to an inventive contribution to the claimed invention of the present application.

In light of the Declaration under 37 C.F.R. § 1.132 and Applicants' remarks, withdrawal of the rejection is respectfully requested.

The Examiner rejected claims 95, 96, 98, 99, 101, 102, 104, 105 and 107-147 under 35 U.S.C. § 102(a) as being unpatentable over Garret *et al.* (*J. of Neurochemistry* 68(4): 1382-1389 (1997)). The Examiner objected to claims 97, 100, 103 and 106 since they depend from rejected claims. Applicants respectfully traverse the objection and rejection.

The Examiner stated that Garret *et al.* "disclose a polynucleotide . . . which encodes a polypeptide which is 99.5% identical to the polypeptide of SEQ ID NO:42" which "comprises at least 200 contiguous nucleotides of SEQ ID NO:41" (Office Action, page 4). Garret *et al.* also disclose, according to the Examiner, a vector, host cell and method of making the polypeptide. The Examiner concluded that since the "polynucleotide was inserted into a vector, which comprises nucleotides encoding regulatory sequences and proteins," then the Garret *et al.* polynucleotide "contains a heterologous regulatory sequence, as well as heterologous polynucleotides" (Office Action, page 5).

Applicants assert that as much of the claimed invention that is disclosed in Garret *et al.* was completed in this country before March 8, 1997, which appears to be the earliest effective date of Garret *et al.* In support of this assertion, Applicants submit herewith a Declaration under 37 C.F.R. § 1.131 by Ewen F. Kirkness and Michael C. Hanna attesting to this fact.

In light of the Declaration under 37 C.F.R. § 1.131 and Applicants' remarks, withdrawal of the rejection is respectfully requested.

Rejections under 35 U.S.C. § 103

The Examiner rejected claims 108, 120, 129 and 141 under 35 U.S.C. § 103(a) as being unpatentable over Davies *et al.* (*Nature* 385: 820-823 (Feb. 1997)) in view of Reichmann *et al.* (*Cell* 71: 1103-1116 (Dec. 1992)). Applicants respectfully traverse the rejection.

The Examiner stated that Davies *et al.* teach "an isolated polynucleotide encoding an amino acid sequence which is 100% identical to amino acids 1-260 of SEQ ID NO:42" and the production of a heterologous polynucleotide using the DNA inserted into a vector (Office Action, page 5). The Examiner acknowledges that Davies *et al.* do not teach heterologous polypeptide production.

To make-up for this deficiency, the Examiner cited Reichmann *et al.* as teaching "the production of heterologous polypeptides by use of a vector containing heterologous polynucleotides" (Office Action, page 5).

The Examiner combined the teachings of Davies *et al.* and Reichmann *et al.* to conclude the following:

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the invention of Davies *et al.*, which teaches an isolated polynucleotide which is 100% identical to SEQ ID NO:41 . . . inserted into a vector as well as a host cell and a method of making said polypeptide . . . by substituting the c-fos gene, which was inserted in-frame into the vector containing the hormone-binding domain of the human estrogen receptor, with the polynucleotide of Davies *et al.* to produce a fusion protein.

One of ordinary skill in the art would have been motivated to substitute the polynucleotide of Davies *et al.* for the c-fos polynucleotide of Reichmann *et al.* since the production of fusion proteins is a well-known method of purifying proteins. There would have been a reasonable expectation of success for a person of ordinary skill in the art to perform the invention of Davies *et al.* using the expression construct of Reichmann *et al.* since DNA digestion and ligation procedures are a widely used and highly successful means of linking DNA molecules.

Office Action, pages 5-6.

As set forth above, and in the Declaration under 37 C.F.R. § 1.132, Davies *et al.* fails to qualify as a reference under 35 U.S.C. § 102(a). Since Davies *et al.* cannot be applied, and Reichmann *et al.* fails to teach the polynucleotides and amino acids set forth in the claims, the rejection cannot stand.

In light of Applicants' remarks and the Declaration under 37 C.F.R. § 1.132 discussed above, withdrawal of the rejection is respectfully requested.

The Examiner rejected claims 114, 126, 135 and 147 under 35 U.S.C. § 103(a) as being unpatentable over Davies *et al.* (*Nature* 385: 820-823 (Feb. 1997)). Applicants respectfully traverse the rejection.

According to the Examiner, Davies *et al.* disclose "an isolated polynucleotide which is 100% identical to the polynucleotide of ATCC Deposit No. 209642" as well as a vector, host cell, and method of making the related polypeptide (Office Action, page 6). The Examiner acknowledged that Davies *et al.* do not teach polypeptide recovery.

The Examiner concluded that:

it would have been obvious to one of ordinary skill in the art at the time the invention was made to have recovered the polypeptide in order to do enzymatic digestion assays of the protein, to produce antibodies and to determine the structure of the protein. There would have been a reasonable expectation of success for a person of ordinary skill in the art to recover the polypeptide since the

methods of recovering polypeptide from cells are well-known,
widely used and highly successful in the art.

Office Action, page 6.

The basis for the failure of Davies *et al.* to qualify as a reference under 35 U.S.C. § 102(a) is set forth above. Since Davies *et al.* cannot be applied, the rejection cannot stand.

In light of Applicants' remarks and the Declaration under 37 C.F.R. § 1.132 discussed above, withdrawal of the rejection is respectfully requested.

Other Matters

On page 2 of the Office Action, the Examiner requested copies of the NCBI Entrez Nucleotide Queries (references AT16-AS20) cited on PTO Form 1449. Copies were originally submitted on August 5, 1998 as indicated by the copy of the date-stamped post-card receipt submitted herewith. Courtesy copies of the requested references are submitted herewith for the Examiner's convenience.

Conclusion

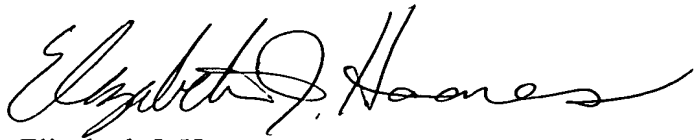
All of the stated grounds of objection and rejection have been properly traversed, accommodated or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for

any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

A handwritten signature in black ink, appearing to read "Elizabeth J. Haanes", written in a cursive style.

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